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UNITED STATES DISTRICT COURT**DISTRICT OF NEVADA**BARBARA HEINRICH and GREGORY
HEINRICH,

Plaintiffs

v.

ETHICON, INC.; ETHICON LLC; and
JOHNSON & JOHNSON,

Defendants

Case No.: 2:20-cv-00166-APG-VCF

**Order Granting in Part Motion to Exclude
Opinion of Brian Flynn****[ECF No. 51]**

This case was part of multidistrict litigation (MDL) assigned to the United States District Court for the Southern District of West Virginia concerning the use of transvaginal surgical mesh to treat stress urinary incontinence (SUI). Plaintiff Barbara Heinrich alleges that she suffered injuries after having the TVT-SECUR (TVT-S) product implanted. The TVT-S was designed and manufactured by defendants Johnson & Johnson and Ethicon, Inc. ECF No. 4. This case was recently remanded from the MDL court with several motions pending .

The plaintiffs seek to exclude the testimony of one of the defendants' experts, Dr. Brian Flynn, on four topics: (1) the cause of Heinrich's sacral pain, central sensitization, and the treatment for those conditions; (2) that the spiral sling implanted in March 2011 caused Heinrich's total incontinence and subsequent incontinence procedures; (3) that an undiagnosed cystocele¹ caused the symptoms for which Heinrich had the TVT-S partially removed in July 2010; and (4) Dr. Flynn's clinical experience with the TVT-S as a basis for his causation opinions.

¹ Generally, a cystocele is a weakening of the supportive tissue between the bladder and the vaginal wall that allows the bladder to bulge into the vagina.

1 The parties are familiar with the facts, so I do not repeat them here except where
2 necessary. I grant the motion with respect to Flynn's opinion regarding the cause of Heinrich's
3 central sensitization. I deny the motion in all other respects.

4 **I. ANALYSIS**

5 In briefing regarding other experts in this case, the parties adopt Judge Goodwin's prior
6 statement of the standard for reviewing motions challenging expert testimony under Federal Rule
7 of Evidence 702 and *Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), so I
8 do the same. *See Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 701-02 (S.D.W. Va. 2014);
9 *Edwards v. Ethicon, Inc.*, No. 2:12-CV-09972, 2014 WL 3361923, at *1-3 (S.D.W. Va. July 8,
10 2014).

11 **A. Tailbone and Back Pain, Central Sensitization, and Pain Management**

12 The plaintiffs argue Dr. Flynn is not qualified to render an opinion on what caused
13 Heinrich's tailbone and back pain or whether the pain management she received was related to
14 the TVT-S. They argue that he admitted at his deposition he is not an expert in central
15 sensitization, could not identify the criteria for it, and does not treat the condition in his practice.
16 They contend that he also testified that he is not an expert in pain management, ketamine
17 infusions, or nerve stimulators used to treat pain, and that he would refer a patient experiencing
18 central sensitization to a pain management specialist.

19 The plaintiffs also object to his opinion that Heinrich's central sensitization was caused
20 by a fall in 2001. They contend he is not qualified to diagnose the source of her pain and, in any
21 event, has no factual basis to trace it to the fall because there is no evidence Heinrich suffered
22 tailbone pain or received treatment for pain for three years prior to her TVT-S implantation.

1 The defendants respond that Dr. Flynn has diagnosed and treated patients with central
2 sensitization. They also argue Dr. Flynn relied on Heinrich's medical records and identified
3 specific complaints of pain and other symptoms when reaching his conclusion that the fall
4 caused the central sensitization. The defendants argue Dr. Flynn is allowed to offer a plausible
5 alternative cause for Heinrich's injuries and he did so by a permissible method of reviewing her
6 symptoms and complaints in her medical history. Alternatively, the defendants argue that if Dr.
7 Flynn is not qualified to identify the cause of her injuries, he is qualified to opine that the TVT-S
8 was not the cause.

9 Dr. Flynn is not qualified to opine on the cause of Heinrich's central sensitization
10 because he has never diagnosed a patient with it, would refer a patient suspected of it to her
11 primary physician for diagnosis, does not treat it, has not reviewed literature on it, cannot
12 identify the criteria for it, and admitted he is not an expert on the condition. ECF No. 51-3 at 60-
13 68. Merely because he has patients with the condition and is familiar with its existence does not
14 qualify him to opine on the cause of Heinrich's central sensitization or the proper treatment of it.
15 His opinion that a fall in 2001 caused Heinrich's central sensitization is therefore excluded.

16 The defendants argue Dr. Flynn nevertheless should be able to opine that the TVT-S did
17 not cause Heinrich's central sensitization. The defendants do not explain how, having no
18 experience with the condition and not being able to identify the criteria for it, Dr. Flynn still may
19 offer an opinion ruling out the TVT-S as the cause. Dr. Flynn may not opine that the TVT-S was
20 not the cause of Heinrich's central sensitization.

21 However, he may offer more limited opinions, such as discussed in his deposition, that
22 the TVT-S does not pass by certain nerves in the body. *See* ECF No. 51-3 at 98-100. Dr. Flynn
23 is a practicing urologist who is board certified in Female Pelvic Medicine and Reconstructive

1 Surgery. ECF No. 56-2 at 7. He spends the majority of his time in a clinical practice and also
2 teaches and researches in the area of female pelvic medicine. *Id.* He has performed more than
3 1,100 procedures for SUI, including the use of mesh implants generally and TVT-S specifically.
4 *Id.* at 7-8. He has spoken and published on the topic of transvaginal mesh. *Id.* He thus is
5 qualified to opine about where the TVT-S is implanted in the body in relation to the surrounding
6 anatomy.

7 **B. Spiral Sling**

8 Following removal of the TVT-S, Heinrich was implanted with a spiral sling by Dr. Raz.
9 The plaintiffs challenge Dr. Flynn's opinion that the spiral sling, not the TVT-S, caused
10 Heinrich's later surgeries for a devastated urethra. According to the plaintiffs, Dr. Flynn bases
11 this opinion entirely on his own experience in implanting spiral slings, which has resulted in
12 complications for his patients. The plaintiffs argue this is an insufficient basis to support his
13 opinion because he admitted at his deposition that in each of the three cases he was referring to,
14 the patient's urethra was already devastated and the sling was used as a salvage procedure. They
15 contend that Dr. Raz similarly had diagnosed Heinrich with a devastated urethra before he
16 implanted the spiral sling as a salvage procedure, and thus the sling could not have caused the
17 devastated urethra.

18 The defendants respond that Dr. Flynn's experience with implanting spiral slings was not
19 the sole basis for his opinion. They contend that he explained at his deposition how Heinrich's
20 condition worsened after placement of the spiral sling.

21 In his report, Dr. Flynn opines that Heinrich "developed refractory incontinence as a
22 result of the spiral sling and Coaptite abscess that destroyed the urethra; eventually leading to
23 urethrectomy," after which she underwent at least seven additional surgeries to address

1 incontinence. ECF No. 51-2 at 17. Dr. Flynn opines that “[n]one of these surgeries were the
2 result of the TVT-Secur mesh, but rather due to the spiral sling. The spiral sling led to a
3 significant escalation of her medical condition.” *Id.* In his report, he states that he has used a
4 spiral sling in only a few cases and each time it has resulted in complications, including a
5 devastated urethra. *Id.* He repeated that at his deposition, indicating that he has implanted a
6 spiral sling only three times, and in each case it was an “end-stage” procedure for patients who
7 had already had multiple surgeries and complications. ECF No. 51-3 at 38-41.

8 Dr. Flynn describes in his report the basis of his disagreement with Dr. Raz that the TVT-
9 Secur started a “chain of events” that led to Heinrich’s multiple surgeries. ECF No. 51-2 at 18.
10 He notes that Heinrich had urinary tract infections before she was implanted with the TVT-S.
11 He opines that her “subsequent peri-urethral abscess occurred after Coaptite and spiral mesh
12 sling,” because her “incontinence was cured for 1 year following the TVT-Secur,” the mesh was
13 partially removed “due to pain, not incontinence,” and after the mesh was partially removed,
14 “her SUI was still mild. This is inconsistent with a devastated urethra. The devastated urethra
15 did not develop until after the spiral sling.” *Id.*

16 He elaborated at his deposition that “at the time the spiral sling was performed, her
17 urethra was not devastated; that I thought there was simpler options that she could have
18 undergone.” ECF No. 51-3 at 46-47. He identified the point in time when he thought her urethra
19 was devastated, which was about 10 months to a year after the spiral sling was implanted when
20 she “developed the periurethral abscess and fluid collection.” *Id.* at 46. He explained that he
21 based that conclusion on the MRI findings, the “periurethral fluid collections that existed in and
22 around her urethra, the severe amount of pain that she had at that time in her pubic bone and in
23 and around her urethra, [and] the degree of incontinence that she had at that time.” *Id.* at 46-47.

1 He also based it on nature of the procedures that were being offered to Heinrich at that point,
2 which “are really only offered for patients with a devastated urethra. So when those
3 conversations were being had with Ms. Heinrich, then that would be suggestive that the urethra
4 was, in fact, devastated at that time.” *Id.* at 49-50. Dr. Flynn thus explained the basis for his
5 opinion, and it was not based solely on his experience with three implantations of the spiral sling
6 in his own patients.

7 His opinion also has some support in other testimony in the record. For example, Dr. Raz
8 was questioned at his deposition about the fact that prior to the spiral sling implant, Heinrich was
9 incontinent with activity, but afterwards she was incontinent with walking, standing, lying, and
10 sleeping. ECF No. 51-5 at 119-20. Thus, her condition worsened following the spiral sling
11 implant, as Dr. Flynn opined. However, his opinion also contradicts some evidence in the
12 record, including Dr. Raz’s notes, which Dr. Flynn acknowledges, that prior to the spiral sling
13 implant, there was “total urinary incontinence on evaluation” and surgical notes indicating that
14 throughout the spiral sling implant procedure the urethra was “total incontinent. Even with a
15 Foley catheter, urine will leak around the urethra meaning total urethral incompetence.” ECF
16 Nos. 51-2 at 12; 51-6 at 2-3. Dr. Raz’s initial evaluation and surgical notes at the time the spiral
17 sling was implanted suggest Heinrich’s urethra was already devastated and that is why Dr. Raz
18 implanted the spiral sling.

19 Dr. Flynn’s evaluation of the medical records and his justifications for his opinion are
20 matters for cross-examination that go to the weight of his testimony, not its admissibility.² I
21 therefore deny this portion of the plaintiffs’ motion.

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23 ² At various points in their brief, the plaintiffs rely on *Williams v. Eighth Judicial District Court of the State of Nevada, ex rel. County of Clark*, 262 P.3d 360 (2011) (en banc). In that case, the Supreme Court of Nevada held as follows:

1 **C. Undiagnosed Cystocele**

2 Dr. Flynn opines that the symptoms Heinrich was experiencing before the TVT-S was
3 removed were caused by an undiagnosed cystocele. The plaintiffs argue this opinion is pure
4 speculation unsupported by any evidence in Heinrich's medical records and instead is based on
5 his opinion that TVT-S does not cause obstruction or retention. They note that he admits her
6 doctor, Dr. Eilber, did not find a cystocele, and "if accurate" that would mean a cystocele did not
7 cause Heinrich's symptoms.

8 The defendants respond that Dr. Flynn explained in his deposition testimony the basis for
9 his conclusion that Heinrich had an undiagnosed cystocele and that his opinion was based on his
10 review of her medical records. They argue he is entitled to offer a plausible alternative
11 explanation for the cause of Heinrich's injuries.

12 In his report, Dr. Flynn opines that the "retention Mrs. Heinrich experienced was, more
13 likely than not, caused in part by her cystocele." ECF No. 51-2 at 23. He acknowledged that Dr.
14 Eilber, who performed the partial removal of the TVT-S in July 2010, "did not find any
15 significant pelvic organ prolapse in 2010, so if that is accurate then any retention she was
16 experiencing at that time would not be caused by cystocele." *Id.* He bases his opinion that there
17 was an undiagnosed cystocele on the fact that in "March 2011, Dr. Raz noted that her cystocele

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19 When a defense expert traverses the causation theory offered by the plaintiff and
20 purports to establish an independent causation theory, the testimony must be
21 stated to a reasonable degree of medical probability However, when a
22 defense expert's testimony of alternative causation theories controverts an
23 element of the plaintiff's prima facie case where the plaintiff bears the burden of
proof, the testimony need not be stated to a reasonable degree of medical
probability, but it must be relevant and supported by competent medical research.
262 P.3d at 362-63. Dr. Flynn stated in his report that he held his opinions "to a reasonable
degree of medical and scientific certainty." ECF No. 51-2 at 26.

1 created a kinking effect in Mrs. Heinrich's mid-urethra." *Id.* He also opines that the TVT-S did
2 not cause the retention because "[s]ingle-incision slings like the TVT-Secur have a rate of urine
3 retention lasting more than six weeks post-operatively that is comparable to that seen with full-
4 length trans-obturator and retropubic mid-urethral slings, and lower than pubovaginal slings or
5 the Burch procedure." *Id.*

6 He testified at his deposition that "the most common causes of obstruction in women are
7 usually incontinence surgery and prolapse." ECF No. 51-3 at 57. He testified that he could not
8 be sure whether there was a cystocele in this case because Dr. Eilber did not perform procedures
9 that could have determined whether reducing the cystocele would have relieved the urinary
10 retention and obstruction problem. *Id.* at 57-58. He stated that due to this lack of testing, his
11 opinions "are based more on [his] history" and experience with the TVT-S and related literature
12 and trials for the device, which show that "it's exceedingly rare to get obstruction or retention
13 from mini-slings, including TVT-Secur. That was one of the many advantages of TVT-Secur
14 and mini-slings and why they were very popular." *Id.* at 59.

15 Dr. Flynn's opinion is grounded in his experience, literature, trials, and Heinrich's
16 medical records. He explains that a cystocele cannot be ruled out because Heinrich's doctor did
17 not perform certain tests and he notes that less than a year later, Heinrich had a cystocele that
18 resulted in kinking of her mid-urethra. He also bases his opinion on the usual causes of urinary
19 obstruction versus the low incidence of obstruction complications from the TVT-S. Whether he
20 properly discounted Dr. Eilber's finding of no prolapse is a matter for cross-examination and
21 goes to the weight of his testimony, not its admissibility. I therefore deny this portion of the
22 plaintiffs' motion.

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D. Dr. Flynn's Experience with TVT-S

The plaintiffs contend Dr. Flynn should be precluded from basing his opinions on his own experience using TVT-S because he refused to provide data on his complication rates, he has no experience with long term complications, and he ignores poor results in his own cases. The defendants respond that Dr. Flynn is an experienced urologist who, like other experts in this case, is allowed to rely on his experience performing hundreds of procedures even if he does not keep exact statistics on his procedures. They also argue that he need not follow his patients for more than a year because patients experiencing complications likely would return to him for a follow-up appointment. The defendants contend Dr. Flynn never testified that he had poor results with TVT-S, he stated only that he improved his own technique in implanting it.

Judge Goodwin reserved ruling on the reliability of Dr. Flynn's safety and efficacy rulings because he did "not have enough information to judge the reliability or relevance of Dr. Flynn's particular experience," and so was "without sufficient information at [that] time to draw the fine line between reliable and unreliable expert testimony on safety and efficacy." ECF No. 81-5 at 9-10. He therefore reserved ruling on this issue. *Id.* at 10.

By separate order, I have adopted Judge Goodwin's order. The parties' case-specific briefing has done little to fill the gaps that led Judge Goodwin to reserve ruling. Consequently, I deny the motion to exclude at this time because a *Daubert* hearing is necessary on the issues the plaintiffs raise regarding whether Dr. Flynn's opinions based on his personal experiences are relevant and reliable.

By separate order, I am directing the parties to confer regarding a schedule for the remainder of this case, including resolution of outstanding issues concerning various experts. As part of the conference, the parties must discuss a *Daubert* hearing for Dr. Flynn, including how

1 long they need to prepare for the hearing, whether any additional briefing is needed, and
2 proposals for scheduling the hearing in light of the parties' and witness's schedules and the
3 current COVID-19 pandemic. The parties must include their proposal for the *Daubert* hearing in
4 the proposed schedule they prepare in relation to my other order.

5 **II. CONCLUSION**

6 I THEREFORE ORDER that the plaintiffs' motion to exclude the testimony of Brian
7 Flynn (**ECF No. 51**) is **GRANTED in part**. Dr. Flynn's opinion regarding the cause of Barbara
8 Heinrich's central sensitization is excluded. The motion is denied in all other respects.

9 I FURTHER ORDER the parties to confer about the scheduling of a *Daubert* hearing for
10 Dr. Flynn as set forth above, and to include their proposal in the schedule they prepare in
11 response to my other order directing the preparation of a schedule for the remainder of the case.

12 DATED this 17th day of April, 2020.



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14 ANDREW P. GORDON
15 UNITED STATES DISTRICT JUDGE
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